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To: Health Care Providers

From: Pejman Talebian, MA, MPH, Director
Immunization Program

Shumethia Seal, MPH, Vaccine Manager
Immunization Program

Date: January 2018

Re: ***REVISED*** Vaccine Restitution Policy Effective January 1, 2018

This memo summarizes MDPH's current Vaccine Restitution Policy.

The Vaccines for Children (VFC) program, a component of each state's medical assistance plan, is considered a Title XIX Medicaid program. Section 1928 of the Social Security Act (42 U.S.C. §1396s) provides for purchase of vaccine for administration to VFC-eligible children – "federally vaccine-eligible children" only. Federal fraud and abuse laws apply to the entire VFC program, and a specific federal protocol must be followed when problems are identified. This protocol must also be followed for problems related to state purchased vaccines.

For more information on fraud and abuse, please see the MDPH document *Guidelines for Compliance with Federal Vaccine Administration Requirements*, Section A.5 (www.mass.gov/dph/imm then click on Vaccine Management.)

The federal protocol described above includes procedures for collecting restitution in certain incidents of vaccine loss. The Massachusetts Department of Public Health (MDPH) implemented a vaccine restitution policy effective January 1, 2011. Examples of the most common vaccine loss requiring restitution have included:

- Not opening vaccine shipments on arrival
- Leaving the refrigerator or freezer door ajar
- Allowing vaccines to expire before use

- Not moving vaccine to a back up unit or facility when a refrigerator or freezer is without power or not functioning properly

Restitution Policy

MDPH acknowledges that providers make good faith efforts to store and handle vaccines appropriately, as outlined in the Guidelines for Compliance (referenced above).

However, MDPH will require providers to provide restitution for any doses of federal or state-purchased vaccines that have been lost due to the provider's failure to properly receive, store, or use vaccines if:

- a. this is the 1st incident and the total loss is over \$10,000, or
- b. this is the 2nd incident (or greater) – regardless of total value, or
- c. it is due to a failure to immediately open a vaccine shipment from McKesson or Merck resulting in damaged vaccine, regardless of total value, or
- d. it is due to a failure to store refrigerated vaccine in a refrigerator or failure to store frozen vaccine in a freezer.

Restitution will require the provider to privately purchase replacement doses of the vaccines that were lost. Listed below are examples of provider negligence that will require financial restitution:

- Failure to open vaccine shipments from McKesson or Merck immediately, resulting in damage to the vaccines.
- Failure to rotate vaccine stock, resulting in expired vaccine.
- Allowing vaccine to expire. Providers must transfer short dated vaccine to another practice or contact the Vaccine Unit 2 months prior to vaccine expiration.
- Using VFC or state-provided vaccines for unapproved groups including patients 19 years and older.
- Freezing vaccines meant to be refrigerated.
- Refrigerating vaccines meant to be frozen.
- Refrigerator or freezer left unplugged, or electrical breaker switched off by provider staff, contractors, or any other individual.
- Refrigerator or freezer door left open or ajar by staff, contractors, or any other individual.
- Vaccine that is left out of the refrigeration unit and becomes non-viable (Always call the Vaccine Management Unit at 617-983-6828 to determine if vaccine can be identified as viable.)
- Any power outages in which the provider fails to act according to their vaccine storage back up plan.
- A refrigerator malfunction in a non-pharmaceutical grade unit that is being used to store vaccines for a pediatric practice.
- Any other handling and storage mistakes by provider staff.

***NOTE: Beginning in January 2018, MDPH requires all pediatric practices (any site that administers at least some vaccine to those <19 years of age, excluding sites that only administer flu vaccine) to have pharmaceutical grade refrigerators for all vaccine storage units in their facility.**

Although there is no specific description of a pharmaceutical grade refrigerator, some of the characteristics include:

- Internal overhead fans to disperse cold air throughout the unit, eliminating cold pockets of air
- Adjustable wire shelves to allow better air flow
- No storage bins, or shelves on door
- Typically, pharmaceutical grade refrigerators have a narrow operating range (less than 2 Celsius degrees or 3 Fahrenheit degrees)
- Electronic digital thermostat
- Micro Processor
- Evaporator Coil

The MDPH will notify the provider concerning the number of doses of each vaccine that must be replaced; vaccine must be replaced on a dose per dose basis. Subsequent vaccine orders from the provider will not be processed by the Vaccine Unit until a copy of the invoice or packing list for the replacement vaccine has been received by MDPH, reviewed, and determined to be adequate.

Please note that the MDPH will only hold providers accountable in situations of provider negligence as outlined above and will not seek restitution for a vaccine loss that occurred due to a circumstance not in the provider's control (i.e. act of nature). Providers will be given due process to dispute cases of avoidable loss. However, MDPH retains the right to make final determinations regarding vaccine restitution.

The MDPH recommends that all health care provider offices contact their insurance companies to verify that they have adequate coverage to cover any type of vaccine loss. This coverage should be at a level adequate to cover the private market cost to fully replace the highest level of vaccine inventory that they could potentially maintain in their offices. This coverage should also be updated on an annual basis as their vaccine formulary changes and vaccine prices go up.

Any questions on this procedure can be addressed by calling the Vaccine Unit at 617-983-6828.